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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,126	06/15/2001	Assaf Govari	BIO-136	8637

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EXAMINER	
SMITH, FANGEMONIQUE A	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
06/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/882,126	GOVARI, ASSAF	
	Examiner	Art Unit	
	Fangemonique Smith	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Remarks filed on March 29, 2010. Claims 1-21 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 5,405,337) in view of Simpson et al. (U.S. Patent Number 6.752.804) and in further view of More (U.S. Patent Number 6,334,093).

In regard to claims 1-5 and 9-15, Stern et al. disclose a tissue heating and ablation system which upon use employs an energy emitting electrode to heat tissue. The system upon use further includes a method for measuring temperature at a site of interest within a patient comprising steps of providing a medical device and placing the medical device within the patient at the site of interest (col. 1, lines 48-67; col. 2, lines 1-49). Stern et al. disclose thermal mapping techniques employed to determine temperature curve coordinates. Stern et al. disclose upon use of the system a voltage is measured at the site of interest and a temperature measurement is taken (col. 5, lines 10-64). Stern et al. disclose the temperature is determined based on an algorithm which includes a resistance value obtained (col. 5; col. 6, lines 1-35). Upon use, the Stern et al. device further includes generating an externally applied field at the patient wherein the frequency

of the generator signal is different than the temperature measurement signal. As described, Stern et al. disclose the features of the Applicant's invention as described above. Although Stern et al. discloses thermal mapping and techniques which indicate position of the medical device, Stern et al. do not specifically disclose the use of a position sensor. Simpson et al. disclose a catheter having a plurality of electrodes, each with multiple thermal sensors attached and used to position the electrodes proximal to biological tissue of interest (Abstract). The plurality of sensors used with the Simpson et al. device provide temperature readings and position determination of the catheter (col. 3, lines 53-67; col. 4,lines 1-18). Simpson et al. further disclose positioning the thermal sensors at the electrode tissue interface to provide sufficient electrical energy to the site of interest without overheating. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue heating and ablation system, similar to that disclosed by Stern et al., to include a position and temperature sensor which determines the temperature at the position sensor, similar to that disclosed by Simpson et al., to provide information regarding the location of the device while enabling the device to be accurately positioned at the target site. The combined references of Stern et al. and Simpson et al. disclose features of Applicant's invention as described above. The combined references do not disclose providing a resistance drift factor to the resistance value. More discloses a method and apparatus for measurement of temperature differences. The More patent discloses a device which accurately resolves extremely small differences in electrical signals by incorporating a drift compensation factor upon measurement of differences in a physical variable such as temperature. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a issue heating and ablation system, similar to that

disclosed by the combined references of Stern et al. and Simspon et al., to include a resistance drift factor, similar to that disclosed by More, to improve the accuracy of the results obtained while maintaining the functionality of the device.

4. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 6,241,724) as modified by Simpson et al. (U.S. Patent Number 6,752,804) in view of More (U.S. Patent Number 6,334,093) and in further view of Acker (U.S. Patent Number 5,833,608).

In regard to claims 6-8, the combined references of Stern et al., Simpson et al., and More disclose a method for measuring temperature at a site within a patient during a medical procedure which includes the features of the Applicant's invention as described above. The combination further describes the medical device being capable of determining a temperature value and temperature sensitivity based on the resistance value. The combined references further disclose performing an ablation procedure at the site with the medical device, however the combined references fail to specifically disclose the use of an AC generator signal to apply a magnetic field to the patient. Acker discloses a magnetic positioning and orientation determining system which uses magnetic fields to deduct the position and orientation of a probe. The system of the Acker patent is used to perform ablation procedures. The device includes a signal generator, which delivers an AC signal to the distal tip of the device. Operation of the device further includes transforming the AC signal into a DC signal upon utilizing a synchronous detector. The generator signal of the Acker device is capable of operating at 3KHz with the temperature measurement signal at 4Hkz. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to include an AC generator and

synchronous detector system, similar to that disclosed by Acker, to deliver an AC signal to a medical device, similar to the device described in the combined references of Stern et al., Simpson et al., and More, as a way to provide a means for superimposing the probe onto a separately acquired image to display the position and orientation of the probe with respect to the patient.

5. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 6,241,724)) as modified by Simpson et al. (U.S. Patent Number 6,752,804) in view of More (U.S. Patent Number 6,334,093) and in further view of Douglass et al. (U.S. Patent Number 5,638,418).

In regard to claims 16-21, the combined references of Stern et al., Simpson et al., and More disclose a method for measuring temperature at a site within a patient during a medical procedure. The combination does not specifically disclose providing a sensitivity drift factor to the temperature value when executing the algorithm. Douglass et al. disclose a system and method that is used to detect temperature. The method includes including an error term to simulate possible drift of resistance values. The system of the Douglass et al. patent uses the resistance drift coefficient during its processing step, which is stored by a memory device of the system. Douglass et al. further disclose a temperature coefficient introduced to adjust the temperature measurement according to the temperature sensitivity of the device in operation. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to apply correction factors, similar to those disclosed by Douglass et al., to an algorithm used to measure temperature similar to the one used by the combined references of

Stern et al., Simpson et al., and More, in order to improve the accuracy of the calculated measurement and reduce sources of variability.

Response to Arguments

6. Applicant argues the prior art references fail to disclose a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor and determining position and/or orientation coordinates of the position sensor based on the signals provided by the positions system using a location system. Examiner respectfully disagrees. The combined references as described in the previous office action disclose a medical system which, upon use, provides determination of temperature and position at a site of interest. The sensors disclosed by Simpson et al. include signals which assist with determining the position of the sensors (col. 3, lines 53-67; col. 4,lines 1-18). The combined references disclose a system which also measures the voltage of the electrodes which are coupled with the sensors of the device; As well as the resistance or thermal resistivity at the site. Applicant's arguments filed March 29, 2010 have been fully considered but they are not persuasive. The rejection stands.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736